Annex 4

Review of literature of DAS-44406-6 soybean in the scope of the authorisation for food and feed uses, import and processing (2019 update)

This annex contains :

Review of literature of DAS-44406-6 soybean in the scope of the authorisation for food and feed uses, import and processing in the EU (2019 update)

PHI-R101-Y19

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1. Summary

An updated systematic search and review of peer-reviewed literature in line with the EFSA Guidance on conducting a systematic review (EFSA, 2010) and taking into account the explanatory note on literature searching (EFSA, 2019), was conducted with the following review question "Does DAS-44406-6 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?".

The review question and the search procedure took into account the product and scope of the authorisation (i.e., authorisation for import into the EU of food and feed containing, consisting of, or produced from DAS-44406-6 soybean) and the objectives of the studies (i.e., assessment of potential adverse effects on human and animal health and the environment of the genetically modified food and feed containing, consisting of or produced from DAS-44406-6 soybean). The systematic searches were performed according to the relevant parts of the EFSA guidance on the application of systematic review methodology to food and feed safety assessments (EFSA, 2010). The fundamental principles followed in this study were (1) methodological rigour and coherence in the retrieval and selection of studies; (2) transparency; and (3) reproducibility. Each search used a procedure that was developed *a priori*.

The systematic search and review of studies published in the scientific literature followed a tiered approach that included: (i) a systematic literature search, (ii) a screening of the retrieved records for relevance to the review question, and (iii) a thorough analysis of potential studies that were considered relevant, if any.

The current systematic search complements the searches previously performed in 2018. Unless outlined below, all portions of the search were conducted according to the methodologies outlined in the previous searches.

The outcome of this analysis showed that no new publications relevant for the review question were identified during the selected time period. No safety concerns were identified for DAS-44406-6 soybean by this literature search exercise.

2. Eligibility/inclusion criteria

Search outputs were manually screened for relevance for the review question: "Does DAS-44406-6 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?". The systematic search uses *a priori* determined eligibility/inclusion criteria indicated in Table 1.

Table 1: Eligibility/inclusion criteria to establish the relevance of retrieved publications based on the review question

Concept	Criteria
Population (taking into account scope of application)	Addressing human and animal health, and/or the environment relevant for the scope of the authorisation. The pathways and level of exposure to the GMO, derived food/feed products, and the intended traits addressed in the study (as assessed under the **I**ntervention/exposure part) are relevant for the intended uses of the GMO and derived food/feed products under regulatory review (e.g. in case of an import application, efficacy of the traits, pest susceptibility, etc. are not considered relevant).
Intervention/exposure	DAS-44406-6 soybean and derived food/feed products, and/or the intended traits (the newly expressed protein(s)).
Intervention/exposure Plant species	In case of studies using GM plants, only studies using soybean are considered eligible. This criterion is not employed for studies regarding the newly expressed proteins.
Intervention/exposure Source organism of the protein	In case of publications using the protein of interest, only publications with the protein from the specific source organism will be considered eligible.
Comparator	If the study is a comparative study that uses plant material as test material, eligible publications must report a non-GM variety.
Outcomes	Effects/impacts on human and animal health, and/or the environment are addressed. Publications addressing other issues such as benefits, socio-economics, ethics, crop protection, detection methods, efficacy, public perception and risk communication are to be excluded using this criterion, as they are not relevant to the risk assessment of GMOs.
Reporting format	Original/primary data are presented in the study. This permits the exclusion of publications that do not present original/primary data (e.g., reviews, editorial, position papers). However, risk assessments from relevant risk assessment bodies (excluding EFSA) will not be excluded.

3. Confirmation of the Suitability of the Search Strings

The previous search strategies were analyzed to ensure that the original search terms were still relevant in the current search engine (described in Section 3.2 below).

3.1. Electronic bibliographic databases

Due to changes in subscriptions to electronic bibliographic databases, updated descriptions are provided below.

Web of Science™ Core collection[1]

Web of Science Core collection is one of the largest citation databases available with over 1.5 billion cited reference connections indexed from high quality peer reviewed journals, books and proceedings[2]. "*Each cited reference is meticulously indexed to ensure that it is searchable and attributes credit to the appropriate publication*". [3]

CABI's CAB Abstracts® and Global Health®[4]

CAB Abstracts gives you instant access to over 9.5 million record[5], with over 350,000 abstracts added each year. Covering publications from over 120 countries in 50 languages, including a number of niche, independent journals, CAB Abstracts gives you the fullest global picture for any subject.[6] This database also includes local publications.

Global Health gives researchers and students unparalleled access to all the world's relevant public health research and practice – providing knowledge without borders. More than 3.3[7] million records, dedicated to public health, with full text hosted for over 100,000 articles including 375 CABI book chapters, over 160 reviews from CABI's very own eJournal CAB Reviews and over 500 news items from 2014 – 2018. New content added each week.[8]

MEDLINE[9]

MEDLINE is the U.S. National Library of Medicine® (NLM) premier bibliographic database that contains more than 25 million references to journal articles in life sciences with a concentration on biomedicine. A distinctive feature of MEDLINE is that the records are indexed with NLM Medical Subject Headings (MeSH®). MEDLINE is the online counterpart to MEDLARS® (MEDical Literature Analysis and Retrieval System) that originated in 1964. MEDLINE is the primary component of PubMed®.[10]

The WoS search engine can access one or more databases depending on your subscription. Web of Science Core collection is an interdisciplinary database covering all sciences including life, physical, health and social sciences which is updated on a daily basis including with articles in-press. CABI covers agriculture, environment, applied life sciences, veterinary sciences, applied economics, food science and nutrition. The subject scope of MEDLINE is biomedicine and health, broadly defined to encompass those areas of the life sciences, behavioral sciences, chemical sciences, and bioengineering needed by health professionals and others engaged in basic research and clinical care, public health, health policy development, or related educational activities.

The WoS search interfaces feature advanced search options which include the use of complex search syntaxes. In addition, Europe PMC (as previously described for 2018 searches) was used to complement the searches as the database allows full text searching of publications stored at Europe PMC.

[1] *Web of Science* is a trademark of *Clarivate Analytics*
[2] https://clarivate.com/products/web-of-science/web-science-form/web-science-core-collection/; Last accessed 14 November 2019
[3] https://clarivate.com/wp-content/uploads/2017/05/d6b7faae-3cc2-4186-8985-a6ecc8cce1ee_Crv_WoS_Upsell_Factbook_A4_FA_LR_edits.pdf; Last accessed 14 November 2019
[4] *CABI*, *CAB Abstracts*, and *Global Health* are trademarks of *C.A.B. International*
[5] Figures as of September 2019
[6] As defined by *CAB;* https://www.cabi.org/publishing-products/cab-abstracts/; Last accessed 14 November 2019
[7] Figures as of September 2019
[8] As defined by CAB; https://www.cabi.org/publishing-products/global-health/; Last accessed 14 November 2019
[9] *MEDLINE* is a trademark of *U.S. National Library of Medicine*
[10] https://www.nlm.nih.gov/bsd/medline.html; Last accessed 14 November 2019

Therefore, it was confirmed that the combination of these sources allows having a broad coverage of publications related to GMO risk assessment.

3.2. Web of Science Search Engine

The Web of Science Core Collection, CABI (CAB Abstracts and Global Health), and MEDLINE databases were accessed using the Web of Science search engine by Clarivate Analytics (referred to as WoS search engine). Search syntaxes were fine-tuned taking into account the specificities of the WoS search engine:

- Preference is given for using a dash ("-") as the WoS search will recognise it as either a dash, a space or a comma. When a dash is utilized, quotation marks around the connected terms are no longer needed (e.g., "acetyl transferase" replaced by acetyl-transferase will retrieve both acetyl transferase and acetyl-transferase), except if there is undesired lemmatisation of the first part of the term.
- Lemmatisation is utilized in the WoS search engine and as thus, terms were evaluated to determine if it was most appropriate to use truncation with a wildcard symbol or to utilize the root word and the lemmatisation feature. For example, using the root term crop returns results that also include the term crops. However, searching for the truncated term crop* returns additional results that are not associated with root word, such as cropland(s), Cropper, CROPWAP, CropEnergies, croping.

The different abstracting literature databases are searched individually using the WoS search engine in order to access all of the relevant fields. The employed search interfaces are used in a way so that each is searched more broadly than the title and abstract, also searching keywords (including indexing keywords, where applicable). For example, the topic search (TS) searches the following fields:

- Web of Science Core collection: Title; Abstract; Author Keywords; Keywords Plus®[11]
- CABI: Abstract; BHTD Crital Abstract; Broad Descriptors; CABICODES Names; Descriptors; English Title; Foreign Title; Geographic Location; Identifiers; Organism Descriptors[12]
- MEDLINE: Title; Vernacular Title; Abstract; Other Abstract; MeSH Terms; Keyword List; Chemical; Gene Symbol; Personal Name Subject; Space Flight Mission[13]

In CABI, indexing terms are included in the Descriptor fields of the record and can be searched for utilising the topic search as described above. Web of Science Core collection does not utilize controlled vocabulary or thesaurus terms, therefore no further additions were made to the developed search string[14].

It was observed that the symbol Ø used in the OECD identifier is sometimes replaced by empty-set, circle-divide, or < 0 > and therefore this was considered in the fine-tuning of the search strings (Appendix 1).

[11] http://images.webofknowledge.com/WOKRS532JR5/help/WOS/hs_topic.html; Last accessed 14 November 2019
[12] http://images.webofknowledge.com/WOKRS532JR5/help/CABI/hs_topic.html; Last accessed 14 November 2019
[13] http://images.webofknowledge.com/WOKRS532JR5/help/MEDLINE/hs_topic.html; Last accessed 14 November 2019
[14] https://support.clarivate.com/ScientificandAcademicResearch/s/article/Web-of-Science-Core-Collection-No-controlled-vocabulary-or-thesaurus-in-assigning-subject-terms?language=en_US

3.3. Conclusions of the suitability of the search strategy

Introduced updates were for consistency or to fine tune the syntaxes to the databases queried. As the updated searches are as sensitive and not more specific than the previous searches, no additional validation was conducted.

4. Results of the literature search exercise

In December 2019, searches against electronic bibliographic databases and manual searches in view of screening of reference lists were performed. The search process is reported in line with EFSA guidance (EFSA, 2010 Appendix B4(2)) in Table 2.

Table 2. Documenting and reporting the search process

Resources	Date of search	Period searched*	Other restrictions	Number of records retrieved
Web of Science Core collection[$]	11 Dec 2019	2018-11 Dec 2019	None	76
CABI[$]	11 Dec 2019	2018-11 Dec 2019	None	63
MEDLINE[$]	11 Dec 2019	2018-11 Dec 2019	None	46
Europe PMC	11 Dec 2019	2018-11 Dec 2019	None	5
Screening reference lists[^]	17 Dec 2019	-	2018-17 Dec 2019[§]	0**

[$] A justification for choosing these search interfaces/databases is provided in Section 3.1. The combination of these sources allows having a broad coverage of publications related to GMO risk assessment.
[^] No risk assessment opinions of the identified regulatory organisations concerning food and feed safety assessment specific DAS-44406-6 soybean, nor any reviews specifically addressing the safety of DAS-44406-6 soybean were identified within the selected literature search period.
§ The time period was applied post-hoc.
** Number of records screened on full text.

The publications retrieved across all methods of searching (Web of Science Core collection, CABI, Medline, Europe PMC, and screening of reference lists) can be found in Appendix 2. In the framework of the reference list screening exercise, no detailed risk assessments regarding the DAS-44406-6 soybean nor any reviews were retrieved that contained information on food and feed safety. Considering that no opinions were published within the selected time period no further screening was performed.

The publications grouped in the Endnote® library were deduplicated. Publications retrieved by the previous searches conducted in the frame of the 2018 annual monitoring report were also removed (see Appendix 2, Section 6). The results of the publication selection process are presented in Table 3.

Table 3. Results of the publication selection process, for the review question

Review question: "Does DAS-44406-6 soybean and derived food/feed products, or the intended traits (the newly expressed protein(s)), have adverse effects on human and animal health and the environment in the scope of the authorisation?"	**Number of records**
Total number of publications retrieved after all searches of the scientific literature (excluding duplicates and publications retrieved by the previous searches conducted in the frame of the 2018 monitoring report)	88
Number of publications excluded from the search results after rapid assessment for relevance based on title and abstract	86
Total number of full-text documents assessed in detail	2
Number of publications excluded from further consideration after detailed assessment for relevance based on full text	2
Total number of unobtainable/unclear publications	0
Total number of relevant publications	0

The 88 unique entries present in the Endnote database (Table 3) were manually screened for relevance to the review question by two independent reviewers using the a priori eligibility/inclusion criteria described in Table 1.

Entries that are deemed to be irrelevant based on title/abstract were not further retained. In cases where the title/abstract did not contain sufficient information, the publication was assessed for relevance at the level of the full text (as listed in Appendix 3). The reason for excluding a result from the second screening is documented and a justification for not further assessing a reference is provided in Table 3.2 in Appendix 3.

No publications were considered relevant (see Appendix 3, Table 3.1). No unobtainable/unclear publications were identified (see Appendix 3, Table 3.3).

5. Conclusion

No publications were identified as relevant for the molecular characterisation, food/feed and environmental safety of DAS-44406-6 soybean within the scope of the authorisation for the defined time period. No safety concerns have been identified for DAS-44406-6 soybean by this literature search exercise.

References

EFSA, **2010**. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.].

EFSA, **2019**. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publication 2019:EN-1614. [62 pp.].

Appendix 1. Detailed search syntaxes for DAS-44406-6 soybean

Web of Science Core collection

Set	Search query
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-444Ø6-6 OR DAS-444-circle-divide-6-6 OR DAS-444empty-set6-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR gmo OR gmos OR lmo OR lmos OR gm OR ge))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR gliphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR max) AND (gmo OR gmos OR lmo OR lmos OR living-modified OR transgen* OR GMHT OR ((GM OR GE OR genetic*) NEAR/5 (modif* OR transform* OR manipulat* OR engineer*))))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2018-2100)
Final Results #6	#4 AND #5

CABI

Set	Search query
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-444Ø6-6 OR DAS-444<o>6-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR

	aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "genetically engineered foods"))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR gliphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipulat* OR transform* OR "genetically engineered foods"))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2018-2100)
Final Results #6	#4 AND #5

MEDLINE

Set	**Search query**
Event #1	TS=(DAS44406* OR DAS-44406 OR DAS-444Ø6-6 OR ((44406 OR Enlist*) AND (soy* OR soja* OR Glycine OR Dow OR Corteva OR herbicid*)))
Proteins #2	TS=((2m-epsps OR 2mepsps OR ((5-enolpyruvylshikimate-3-phosphate-synthase OR epsps OR 5-enol-pyruvyl-shikimate-3-phosphate-synthase OR EPSP-synthase) AND modified AND protein AND (maize OR corn OR zea OR mays)) OR (phosphinothricin AND (acetyltransferase OR acetyl-transferase)) OR (pat AND phosphinothricin) OR aad-12 OR aryloxyalkanoate-dioxygenase-12) AND (Streptomyces OR viridochromogenes OR Delftia OR acidovorans OR soy* OR soja* OR glycine OR (((herbicid* AND (genetical* NEAR/3 modif*)) OR GMHT) AND (crop OR plant OR food OR feed)) OR lmo OR lmos OR ge OR "Food, Genetically Modified"))
Traits #3	TS=((glyphosate* OR Roundup OR "Round-up" OR glyfosate* OR gliphosate* OR glifosate* OR ((2-4-D OR AOPP) AND herbicid*) OR 2-4-dichlorophenoxyacetic-acid OR 2-4-dichlorophenoxy-acetic-acid OR aryloxyphenoxypropionate OR aryloxyphenoxy-propionate OR (fop AND (herbicid* or aryloxyphen*)) OR quizalofop OR haloxyfop OR glufosinate* OR gluphosinate* OR (liberty* AND herbicid*)) AND (toler* OR resist* OR protect*) AND (soy* OR soja* OR Glycine OR

	max) AND (GMHT OR transgen* OR engineer* OR lmo or lmos OR ge OR manipulat* OR transform* OR "Food, Genetically Modified"))
#4	#1 OR #2 OR #3
Reporting Period #5	PY=(2018-2100)
Final Results #6	#4 AND #5

Europe PMC

(DAS44406 OR DAS444Ø6 OR "das-44406" OR "das-444Ø6" OR "44406 soy*" OR "444Ø6 soy*" OR "soy* 44406" OR "soy* 444Ø6" OR "Enlist E3") AND (FIRST_PDATE:[2018-01-01 TO 2020-12-31])

Appendix 2. Entries retrieved by the performed searches to literature databases for DAS-44406-6 soybean within the indicated search period

Note: the numbering of the references in the different appendixes is independent of each other (e.g. a certain reference might be called EFSA 2019a in one appendix and EFSA 2019b in another)

1. Entries retrieved using Web of Science Core collection

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Chorna IV, Dronik GB, Lukashiv TO and Yuzkova VD, 2019. Oxidatively modified proteins in kidneys of rats fed with glyphosate-resistant genetically modified soybean and the herbicide Roundup. Regulatory Mechanisms in Biosystems 10, 319-325.

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Costa NV, Moratelli G, Ferreira SD, Salvalaggio AC and Rodrigues-Costa ACP, 2018. RESISTANCE TO GLYPHOSATE IN POPULATIONS OF Digitaria insularis. Planta Daninha 36, 9.

Dauer J, Hulting A, Carlson D, Mankin L, Harden J and Mallory-Smith C, 2018. Gene flow from single and stacked herbicide-resistant rice (Oryza sativa): modeling occurrence of multiple herbicide-resistant weedy rice. Pest Management Science 74, 348-355.

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Appendix 3. Publications screened for relevance based on the full text

Table 3.1. Report of all relevant publications retrieved after detailed assessment of full-text documents for relevance

Category of information/ data requirement(s)	Reference (Author, year, title, source)
None	Not applicable

Table 3.2. Report of publications excluded from the risk assessment after detailed assessment of full-text documents

Reference (Author, year, title, source)	Reason(s) for exclusion based on eligibility/inclusion criteria listed in Table 1
Anastassiadou M, Brancato A, Cabrera LC, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A, Verani A and European Food Safety Authority EFS, 2019. Setting an import tolerance for 2,4-D in soyabeans. Efsa Journal 17, 20.	Population (setting import tolerance); Reporting format (not primary research)
Larue CT, Goley M, Shi L, Evdokimov AG, Sparks OC, Ellis C, Wollacott AM, Rydel TJ, Halls CE, Van Scoyoc B, Fu XR, Nageotte JR, Adio AM, Zheng MY, Sturman EJ, Garvey GS and Varagona MJ, 2019. Development of enzymes for robust aryloxyphenoxypropionate and synthetic auxin herbicide tolerance traits in maize and soybean crops. Pest Management Science 75, 2086-2094.	Intervention/Exposure (Not on DAS-44406-6 soybean)

Table 3.3. Report of unobtainable/unclear publications

Reference (Author, year, title, source)	Description of (unsuccessful) methods used to try to obtain a copy of the publication
None	Not applicable

Summary of a recent relevant paper for DAS-44406-6 soybean

Table 1: Review of a recent relevant paper in 2009/770/EC format: Food/Feed safety (Cicchillo et al.)

Publication	**Summary of research and results**[1]	**Protection goal**	**Observed parameter**	**Adverse effects**	**Feedback on initial risk assessment**
Cicchillo, R.M., Beeson, W.T., McCaskill, D.G., Shan, G., Herman, R.A., Walsh, T.A.. Identification of Iron-Chelating Phenolics Contributing to Seed Coat Coloration in Soybeans [Glycine max (L.) Merrill] Expressing Aryloxyalkanoate Dioxygenase-12, Under Review.	As indicated by the authors, soybeans genetically modified to express aryloxyalkanoate dioxygenase-12 (AAD-12), an enzyme that confers tolerance to the herbicide 2,4-D, can sometimes exhibit a darker seed coat coloration than equivalent unmodified soybeans. The authors investigated the biochemical basis for this coloration "in a non-commercial transgenic event, DAS-411Ø4-7 that exhibited more pronounced AAD-12-associated seed coat coloration than the commercial event, DAS-444Ø6-6." The authors report that "Analysis of color-enriched seed coat fractions from DAS-411Ø4-7 showed that the color was due to localized accumulation of iron-chelating phenolics, particularly the isoflavone genistin, that are associated with seed coat pectic polysaccharide and produce a brown chromophore. The association between genistin, iron, and pectic polysaccharide was characterized using a variety of analytical methods. Darker seeds from commercial soybean event DAS-444Ø6-6 also show higher genistin content localized to the darker colored portions of the seed coat (with no increase in whole seed genistin levels)."	Food/Feed safety	Darker seed coat coloration	None	No change

[1] Text between double quotes is an excerpt from the above-mentioned paper.